



JUL 26 2011

K111582

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: June 3, 2011

Submitter: GE Healthcare
9900 Innovation Dr
Wauwatosa, WI 53226

Primary Contact Person: Bryan Behn
Regulatory Affairs Manager
GE Healthcare
T:(414)721-4214
F:(414)918-8275

Alternate Contact Person: Seiji Oikawa
Regulatory Affairs Specialist
GE Healthcare Japan Corporation
T: +81-42-585-5123
F: +81-42-585-5950

Device: Trade Name: Logiq S8 Ultrasound System

Common/Usual Name: Logiq S8

Classification Names: Class II

Product Code: Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Predicate Device(s): K092271 Logiq E9 Diagnostic Ultrasound System
K052441 Logiq 7 Diagnostic Ultrasound System

Device Description: The LOGIQ S8 is a full featured, general purpose diagnostic ultrasound system which consists of a mobile console approximately 62 cm wide, 88 cm deep and 175 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 9-inch LCD touch screen and color 19-inch LCD image display.

Intended Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal and Intraoperative (abdominal, thoracic, vascular and neurosurgical).



GE Healthcare
510(k) Premarket Notification Submission

Technology: The Logiq S8 employs the same fundamental scientific technology as its predicate devices

Determination of Substantial Equivalence: Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. Logiq S8 and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Logiq S8, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Logiq S8 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 W. Innovation Dr., RP-2138
WAUWATOSA WI 53226

JUL 26 2011

Re: K111582
Trade/Device Name: Logiq S8 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: May 20, 2011
Received: June 6, 2011

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Logiq S8 Ultrasound System, as described in your premarket notification:

Transducer Model Number

C1-5-D
9L-D
ML6-15-D
M5S-D
IC5-9-D

3CRF-D
L8-18i-D
S4-10-D
P2D
P6D

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy, Ph.D. at (301) 796-XXXX.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)



GE Healthcare
510(k) Premarket Notification Submission

510(k) Number (if known):

Device Name: Logiq S8

Indications for Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal and Intraoperative (abdominal, thoracic, vascular and neurosurgical).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NA
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and
Safety

510(k) Number K111582



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
GE Logiq S8 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	N	N	N	N	N	N	N	N	N	N	5,6,9
Abdominal ^[1]	N	N	N	N	N	N	N	N	N	N	3,5,6,9
Pediatric	N	N	N	N	N	N	N	N	N	N	3,5,6,9
Small Organ ^[2]	N	N	N	N	N	N	N	N	N	N	3,5,6,9
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N	5,6,9
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	5,6,9
Cardiac	N	N	N	N	N	N	N	N	N	N	
Peripheral Vascular	N	N	N	N	N	N	N	N	N	N	3,5,6,9
Musculo-skeletal Conventional	N	N	N	N	N	N	N	N	N	N	3,5,6,9
Musculo-skeletal Superficial	N	N	N	N	N	N	N	N	N	N	3,5,6,9
Other ^[4]	N	N	N	N	N	N	N	N	N	N	3,5,6,9
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]	N	N	N	N	N	N	N	N	N	N	3,5,6,9
Transvaginal	N	N	N	N	N	N	N	N	N	N	3,5,6,9
Transurethral											
Intraoperative ^[9]	N	N	N	N	N	N	N	N	N	N	3,5,6,9
Intraoperative Neurological	N	N	N	N	N	N	N	N	N	N	
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA;

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

Mary S. Patel
(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K111582



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Logiq S8 with C1-5-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	5,6,9
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Pediatric	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P	P	P	P	P	P	P	P	3,5,6,9
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

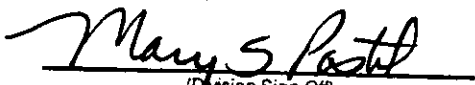
N = new indication; P = previously cleared by FDA(K092271)

- Notes:
- [1] Abdominal includes Renal, GYN/Pelvic.
 - [2] Small organ includes breast, testes and thyroid
 - [3] Elastography Imaging - Elasticity.
 - [4] Other use includes Urology/Prostate
 - [5] 3D Imaging mode
 - [6] Needle guidance imaging
 - [7] Includes infertility monitoring of follicle development
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)


(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K111582



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Logiq S8 with 9L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P		P	P	P	P	P		5,6,9
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	3,5,6,9
Pediatric	P	P	P		P	P	P	P	P	P	3,5,6,9
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	3,5,6,9
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	3,5,6,9
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[5]											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K092271)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

Mary S. Patel
(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K111582



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Logiq S8 with ML6-15-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric	P	P	P		P	P	P	P	P	P	3,5,6,9
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	3,5,6,9
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	9
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	3,5,6,9
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[6]											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA(K092271)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

Mary S Patel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Logiq S8 with M5S-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	5,6,9
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	5,6,9
Pediatric	P	P	P	P	P	P	P	P	P	P	5,6,9
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	9
Cardiac	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA(K092271)

- Notes:
- [1] Abdominal includes Renal, GYN/Pelvic.
 - [2] Small organ includes breast, testes and thyroid
 - [3] Elastography Imaging - Elasticity.
 - [4] Other use includes Urology/Prostate
 - [5] 3D Imaging mode
 - [6] Needle guidance imaging
 - [7] Includes infertility monitoring of follicle development
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

Mary S. Patel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Logiq S8 with IC5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P		P	P	P	P	P	P	5,6,9
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P		P	P	P	P	P	P	3,5,6,9
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]	P	P	P		P	P	P	P	P	P	3,5,6,9
Transvaginal	P	P	P		P	P	P	P	P	P	3,5,6,9
Transurethral											
Intraoperative ^[9]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

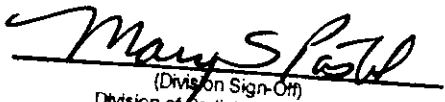
N = new indication; P = previously cleared by FDA(K092271)

- Notes:
- [1] Abdominal includes Renal, GYN/Pelvic.
 - [2] Small organ includes breast, testes and thyroid
 - [3] Elastography Imaging - Elasticity.
 - [4] Other use includes Urology/Prostate
 - [5] 3D Imaging mode
 - [6] Needle guidance imaging
 - [7] Includes infertility monitoring of follicle development
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)


(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111582



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Logiq S8 with 3CRF-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	N	N	N		N	N	N	N	N	N	5,6,9
Abdominal ^[1]	N	N	N		N	N	N	N	N	N	5,6,9
Pediatric	N	N	N		N	N	N	N	N	N	5,6,9
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	N	N	N		N	N	N	N	N	N	5,6,9
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[5]											
Transvaginal											
Transurethral											
Intraoperative ^[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

610K

K111582



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Logiq S8 with L8-18i-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P		P	P	P	P	P	P	3,5,6,9
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	3,5,6,9
Pediatric	P	P	P		P	P	P	P	P	P	5,6,9
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	3,5,6,9
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]											
Transvaginal											
Transurethral											
Intraoperative ^[8]	P	P	P		P	P	P	P	P	P	3,5,6,9
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA(K092271)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

Mary S. Stahl
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K111582



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Logiq S8 with S4-10-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	N	N	N	N	N	N	N	N	N	N	5,6,9
Abdominal ^[1]	N	N	N	N	N	N	N	N	N	N	5,6,9
Pediatric	N	N	N	N	N	N	N	N	N	N	5,6,9
Small Organ ^[2]	N	N	N	N	N	N	N	N	N	N	5,6,9
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N	5,6,9
Adult Cephalic											
Cardiac	N	N	N	N	N	N	N	N	N	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

Mary S. Stahl
(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K111582



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Logiq S8 with P2D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic			P	P							
Cardiac			P	P							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[6]											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											


N = new indication; P = previously cleared by FDA(K092271)

- Notes:
- [1] Abdominal includes Renal, GYN/Pelvic.
 - [2] Small organ includes breast, testes and thyroid
 - [3] Elastography Imaging - Elasticity.
 - [4] Other use includes Urology/Prostate
 - [5] 3D Imaging mode
 - [6] Needle guidance imaging
 - [7] Includes infertility monitoring of follicle development
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)


(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111582



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Logiq S8 with P6D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic			P	P							
Cardiac			P	P							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA(K092271)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

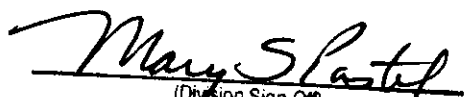
[9] Volume navigation

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)


(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510k K111582